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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/552,272 04/19/00 FANG

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EXAMINER

LARSON, T

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/552,272

Applicant(s)

FANG ET AL.

Examiner

Thomas G. Larson, Ph.D.

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1635

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/15/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 29-37, 51, 52 and 54-56 is/are rejected.
- 7) ☒ Claim(s) 28, 38-50 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

2. The document designated "AA" on the PTO-1449 submitted with the information disclosure statement filed 4/19/00 has been considered only to the extent possible without an English translation.

3. The disclosure is objected to because of the following informalities:
The continuing data in the first paragraph should be updated to include the filing date of all applications, the issued patent numbers, whether or not an application is abandoned. Additionally, priority to application number 07/852,013 is claimed in the first paragraph, but not on the signed copy of the declaration filed 01/05/01.

Appropriate correction is required.

4. The following is a quotation of the appropriate paragraph of 35 U.S.C. 135 that forms the basis for the rejections under this section made in this Office action:

(b)(1) A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

5. Claims 1-6 are rejected under 35 U.S.C. 135(b)(1) as not being made prior to one year from the date on which U.S. Patent Nos. 5,654,169 and 5,726,039 were granted.

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Issued US Patent Nos. 5,654,169 and 5,726,039 both claim isolated nucleic acids that comprise SEQ. ID. NO: 3, which is the sequence of a 290 bp portion of the cspA gene that comprises the promoter and encodes nucleotides +1 to +95 of the 5' UTR ('169 at col. 10, lns. 12-16; '039 patent at col. 11, lns. 41-46; Fig. 7, both patents). See claims 1, 3, 7, and 9 of the '169 patent and claims 1 and 3 of the '039 patent. The promoter fragment identified by SEQ. ID. NO: 3 enhances expression of a heterologous coding region, as shown in Fig. 2 of each patent (construct designated "EL"). This sequence includes the "cold box" at nucleotides +1 to +11 of the cspA 5' UTR, as claimed in claims 4 and 5 of the instant application. In as much as the structures are the same, all functional properties of the sequence set forth in the specification (p. 25, ln. 16, to p. 26, ln. 22) are also expected to be present. See MPEP 2112 & 2112.01. Therefore, the invention now presented in claims 1-6 is the same or substantially the same as the inventions claimed in US Patent Nos. 5,654,169 and 5,726,039, as per 37 CFR 1.601(n). Note MPEP 2301.02.

US Patent Nos. 5,654,169 and 5,726,039 were issued 8/5/97 and 3/10/98, which was more than one year prior to the filing of this application on 4/19/2000. Therefore, these claims do not meet the criterion set forth in 35 USC 135(b)(1) for an interference, absent evidence to the contrary, and may not be presented for examination. See MPEP 2300.01.

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-22 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al.

Claims 1-22 are drawn to an isolated nucleic acid comprising various portions of the *cspA* gene or of an unspecified cold-shock gene including at least a portion of the 5' UTR or specific control elements within the UTR and a cold-shock inducible gene. It is presumed by "cold-shock inducible gene" in claims 20-22 refers to the coding region of a cold-shock inducible gene under the transcriptional control of the regulatory region of the transcriptional control elements recited in the claims from which claims 20-22 depend. Claims 35-37 are drawn to an *E. coli* host comprising the vector.

Goldstein et al. disclose the sequence of a nucleic acid encoding the entire *cspA* gene which is cloned in plasmid vector pJG01 (Fig. 5). The sequence includes a portion encoding the entire 5'UTR which includes the "cold box" the Shine-Dalgarno box, the "upstream box" and the "downstream box". In as much as all claimed structures are present in the isolated nucleic acid and/or vector, all claimed

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functions are presumed to be present, as per MPEP 2112 & 2112.01. Goldstein et al. disclose an E. coli host comprising the vector pJJG01 (p. 285, col 1, lns. 3-5).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 15, 17, 20-27, 29-34, 51, 52, and 54-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite for reciting "comprising having".

Claim 17 is confusing because it reties the "construct of claim 16", but claim 16 is drawn to a "nucleic acid vector".

Claims 20-25 and 29-34 are confusing because the context of the claims appears to indicate that the coding region of the gene is inserted into the vector, but the actual language leaves it unclear if it is the coding region or the entire gene, including the gene's regulatory elements.

Claim 20 is confusing for reciting "said the gene".

Claims 22 and 25 are indefinite for reciting "said gene" because claim 19, from which they depend, recites both "a gene" and "a cold shock inducible gene" making it unclear what the antecedent is for "said gene".

Claims 26 and 27 (and the claims dependent thereon) are indefinite for reciting "said 5' UTR" because there is no antecedent basis for the term in either claim or in the claims from which they depend.

Claims 51 and 52 are indefinite because they do not indicate how the gene is to be inserted into the vector. For example, it is unclear if they are to be inserted into the restriction site for inserting a heterologous gene or if they are to be inserted randomly. Further, it is not clear if it is the coding region or the entire gene that is to be inserted, and it is not clear if it is to be inserted so that it is expressed under the regulation of the cold-shock control regions present in the vector.

Claims 54-56 are confusing because they appear to be drawn to a method of using the vector of claim 50 to over express a gene. However, the vector of claim 50 does not have a gene inserted in the expression cassette, as evidenced by claims 51 and 52.

10. Claims 28, 38-50 and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The OFFICIAL FAX numbers are (703) 308-4242 and (703) 308-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper

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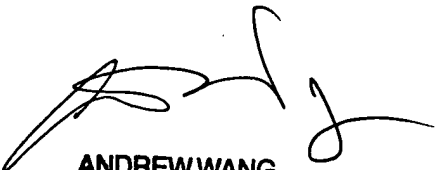
by FAX, the original copy should be retained by the applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office.

Unofficial papers, such as draft responses and proposed amendments, may be transmitted directly to the examiner's computer at (703) 746-7019. If an official paper is to be faxed to this number, it is recommended that the examiner be notified before doing so.

Any inquiry concerning this communication or earlier communications should be directed to Thom Larson, whose telephone number is (703) 308-7309. The examiner normally can be reached Monday through Friday from 9:00 AM to 5:30 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist, whose telephone number is (703) 308-0196.

Thomas G. Larson, Ph.D.
Examiner



ANDREW WANG
PRIMARY EXAMINER